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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,011

12/19/2005

Jan Grund-Pedersen

4145-000006/US

6863

30593 7590 03/14/2008
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EXAMINER

GEBREMICHAEL, BRUK A

ART UNIT

PAPER NUMBER

3714

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,011	Applicant(s) GRUND-PEDERSEN ET AL.	
	Examiner BRUK A. GEBREMICHAEL	Art Unit 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/03/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/03/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

2. Claims 20, 22-24 and 26-27 are objected to because of the following informalities:

Regarding claim 20, the phrase “control unit an said interface unit” in line 3 of this claim is believed to be in error for -- control unit and interface unit --, and also in line 7 of this claim, the phrase “inter face unit” is believed to be in error for -- interface unit --.

Regarding claims 22-24, the phrase “visualisation” in line 17 of claims 22 and 24 is believed to be in error for -- visualization --.

Regarding claims 26-27, the phrase “moans” in line 6 of claim 26 is believed to be in error for -- means --. Appropriate correction is required.

Claim 23 is further objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

However, for examination purpose, the Examiner assumes claim 23 to be dependent on claim 22.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 25 is rejected under 35 U.S.C. 101 because the claimed invention is drawn to a non-statutory subject matter. The claimed limitation “propagated signal” is a non-

statutory subject matter as "signal" is not a process, machine, manufacture or composition of matter.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-25 and 29-30, the phrase "said user" in claims 1, 13, 20, 22, 24-25 and 29-30 make the claims indefinite as there is insufficient antecedent basis for this phrase in the claims. In addition,

Regarding claims 5 and 15, the claims recite the limitation "unique features at the distal end of a tool", (line 2 of claims 5 and 15). This makes the claims indefinite as it is not clear which features are included in the claim.

Regarding claims 6, 8, 16 and 18 the phrase "etc" in line 3 of the claims make the claims indefinite as it is not clear what limitations are included in claimed invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects

for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-27 and 29-30 are rejected under 35 U.S.C. 102(e) as being unpatentable over Anderson 2002/0168618.

Anderson discloses the following claimed limitations:

Regarding claim 1, an interventional procedure simulation system, comprising a control unit and an interface unit (FIG 4), said control unit communicating with said interface unit to simulate handling of a number of simulated nested instruments simultaneously interfaced by said interface unit (Para.0018) and, said instruments being arranged to move and rotated independently of each other and said movements and rotations being propagated to the other instruments (Para.0018 and Para.0035), said control unit further comprising an instruction set comprising a first instruction set for handling and processing input from said user based on said input, generating a second instruction set for controlling said interface (Para.0125, lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0125, lines 17-19), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), and a third instruction set for generating control signals relating to an interaction between said simulated instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21),

Regarding claim 2, said interventional procedure is at least one of a diagnostic, a cardiovascular or endovascular simulation system (see Abstract lines 5-8 and Para.0012, lines 1-4),

Regarding claim 3, a user's movements of said instruments, a surrounding simulated anatomy and other present instruments, affect a shape of an instrument simulated and displayed (Para.0020),

Regarding claim 4, each instrument collisions with simulated surrounding calculations are executed by said control unit, which affects the shape and position of said instrument in said simulated body part (Para.0205 and Para.0206, lines 1-8),

Regarding claim 5, wherein an instrument is a distal part of a tool, or unique features at the distal end of a tool (Para.0036, lines 1-10),

Regarding claim 6, wherein different instrument types can be used comprising balloons, stems, electrodes, wires, catheters, distal protection, etc (see Para.0018, lines 3-8),

Regarding claim 7, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claims 8 and 9, the properties of said instruments further describe interaction with surrounding geometry, visual properties, stiffness, shape etc, and wherein simulated properties of said instrument are altered in real-time (Para.0034, lines 3-13),

Regarding claim 10, the system comprises a model used for rendering objects depending on properties to be displayed and a collision model for computing collisions between the simulated instrument and body part (Para.0200 and Para.0205),

Regarding claim 11, a model of said body or part of said body part is a three-dimensional data obtained through a body scanning (Para.0021, lines 1-3 and Para.0128, lines 1-4),

Regarding claim 12, the instrument movements and rotations interact simulated with other instruments (Para.0035 and Para.0157, lines 9-13).

Regarding claim 13, a method for simulating an interventional procedure (Para.0032, lines 1-8), comprising the steps of providing a control unit and an interface unit (FIG 4), said control unit communicating with said interface unit to simulate handling of a number of nested instruments simultaneously interfaced by said interface unit (Para.0018) and that each nested tool can be moved and rotated independently of the other and said movements and rotations are propagated to other instruments (Para.0035), providing a first instruction set for handling and processing input from said user, generating a second instruction set based on said input, for controlling said interface (Para.0125, lines 7-14), retrieving information on said instrument comprising a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), providing a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6, and Para.0124, lines 5-9), and generating control signals relating to interaction between said instrument and a surrounding geometry by a third instruction set (Para.0034, lines 3-10 and Para.0125, lines 19-21).

Regarding claim 14, changing instrument simulated and displayed based on a user's movements of said instruments, a surrounding simulated anatomy and other

present instruments, effect a shape of an instrument simulated and displayed
(Para.0020, lines 7-16 and Para.0034, lines 3-13),

Regarding claim 15, wherein an instrument is a distal part of a tool, or unique features at the distal end of a tool (Para.0036, lines 1-10),

Regarding claim 16, wherein different instrument types can be used comprising balloons, stents, electrodes, wires catheters, distal protection, etc (see Para.0018, lines 3-8),

Regarding claim 17, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claim 18, wherein the properties of said instruments further describe interaction with surrounding geometry, visual properties, stiffness, shape etc (Para.0035 and Para.0157, lines 9-13),

Regarding claim 19, wherein simulated properties of said instruments are altered in real-time (Para.0020, lines 7-14 and Para.0036, lines 6-16),

Regarding claim 20, a system for an interventional procedure simulation, said system comprising a control unit and an interface unit (FIG 4), the system further comprising means for communication between said control unit and said interface unit means in said interface unit to simulate handling of a number of nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018, and Para.0035), interface member for receiving input from said user, means for handling and processing said input (Para.0020, lines 7-14), means for

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controlling said interface (Para.0022, lines 1-9), a first database for storing characteristics for said instruments (Para.0084, lines 10-16 and also Para.0125, lines 17-19), second database for storing characteristics about a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-10), and means for generating control signals relating to an interaction between said simulated instruments and a surrounding geometry relating to a part of said simulated body part (Para.0034, lines 3-10 and Para.0125, lines 19-21),

Regarding claim 21, wherein said characteristics about a body part to be simulated are obtained through a scanning process (Para.0021, lines 1-3 and Para.0128, lines 1-4),

Regarding claim 22, a computer program for interventional procedure simulation in a system comprising a control unit and an interface unit (FIG 4), said program comprising communication instruction set for communication between said control unit and said interface unit (Para.0114, lines 1-6 and FIG 3), a first instruction set for simulating handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035), said control unit further comprising an instruction set comprising a second instruction set for handling and processing input from said user, a third instruction set for controlling said interface (Para.0125, lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an

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interaction between said simulated nested instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21), and a fifth instruction set for outputting simulation on a visualisation member (see Para.0097, lines 4-10).

Regarding claim 23, a program storage device readable by a machine and encoding a program of instructions for executing the computer program for interventional procedure simulation according to claim 22 (Para.0006 and Para.0125, lines 1-7).

Regarding claim 24, a computer readable medium having computer readable program code embodied therein to enable an interventional procedure simulation in a system (Para.0006 and Para.0125, lines 1-7) comprising a control unit and an interface unit (FIG 4), said program comprising a communication instruction set for communication between said control unit and said interface unit (Para.0114 and FIG 3), a first instruction set for simulating handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035), said control unit further comprising an instruction set, comprising a second instruction set for handling and processing input from said user, a third instruction set for controlling said interface (see Para.0125 lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6, and Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an interaction between said simulated nested

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instruments and a surrounding geometry relating to a part of said simulated body part (Para.0033, lines 1-6 and Para.0124, lines 5-9), and a fifth instruction set for outputting simulation on a visualisation member (Para.0097, lines 4-10).

Regarding claim 25, a propagated signal for comprising a digitalized program code embodied therein to enable an interventional procedure simulation in a system (Para.0006 and Para.0125, lines 1-7) comprising a control unit and an Interface unit (FIG 4), said program comprising a digitalized communication instruction set for communication between said control unit and said interface unit (Para.0114 and FIG 3), a digitalized first instruction set for simulating handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interlaced by said interface unit (Para.0018 and Para.0035), said control unit further comprising an instruction set, comprising a digitalized second instruction set for handling and processing input from said user, a digitalized third instruction set for controlling said interface (Para.0125, lines 7-14), a digitalized first access code for accessing a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a digitalized second access code for accessing a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a digitalized fourth instruction set for generating control signals relating to an interaction between said simulated nested instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21), and a digitalized fifth instruction set for outputting simulation on a visualization member (Para.0097, lines 4-10) ,

Regarding claim 26, a system for an interventional procedure simulation, said system comprising a control unit and an interface unit (FIG 4), the system further comprising means for communication between said control unit and said interface unit for receiving at least one instrument used in said interventional procedure (Para.0018), means for receiving three-dimensional information on a body part to be simulated (Para.0021, lines 1-3 and Para.0128, lines 1-4), and means for generating control signals relating to an interaction between said instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21),

Regarding claim 27, wherein said three-dimensional information is obtained through a scanning process (Para.0021, lines 1-3 and Para.0128, lines 1-4),

Regarding claim 29, a method of an interventional procedure training, using a system comprising a control unit and an interface unit (Para.0032, lines 1-4 and FIG 4) the method comprising using an interventional procedure tool to be simulated in said interface device (Para.0018) simulating an interaction between said nested instruments, independently movable and rotatable, and a surrounding geometry relating to a part of said simulated body part, and using said simulation for training said user (Para.0018 and Para.0035),

Regarding claim 30, a method of facilitating an interventional procedure training, using a system comprising a control unit and an interface unit (Para.0032, lines 1-4 and FIG 4), the method comprising using an interventional procedure tool to be simulated in said interface device (Para.0018), simulating an interaction between said nested instruments, independently movable and rotatable, and a surrounding geometry

relating to a pat of said simulated body part, and using said simulation for training said user (Para.0018 and Para.0035).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson 2002/0168618 in view of Liang 2004/0015070.

Regarding claim 28, Anderson discloses the following claimed limitations: a system for an interventional procedure simulation learning, said system comprising a control unit and an interface unit, (FIG 4) the system further comprising: means for communication between said control unit and said interface unit for receiving at least one instrument used in said interventional procedure (Para.0018), means for receiving three-dimensional information on a body part to be simulated (Para.0021, lines 1-3 and Para.0128, lines 1-4), means for generating control signals relating to an interaction between said instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21).

Even if Anderson does not explicitly disclose, means for recording said simulation, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to recognize the fact that the general purpose computer used in Anderson's invention (Para.0125, lines 1-6) records the simulation.

However, Liang discloses a computer aided treatment invention that teaches, means for recording said simulation (Para.0010 and Para.0013, lines 5-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the invention of Anderson in view of Liang by incorporating a computer readable storage in order to store the three dimensional images of a given intervention procedure so that the user would use this stored procedure for future retrieval, examination and comparison, as taught by Liang.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruk A. Gebremichael whose telephone number is (571)270-3079. The examiner can normally be reached on Monday to Friday (7:30AM-5:00PM) ALT. Friday OFF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571) 272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruk A Gebremichael/
Examiner, Art Unit 3714
/B. A. G./
Examiner, Art Unit 3714

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3714

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